

UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF TEXAS  
Fort Worth Division

Outsourcing Facilities Association, *et al.*,

Plaintiffs,

v.

U.S. Food and Drug Administration, *et al.*,

Defendants, and

Eli Lilly and Company,

Intervenor-Defendants.

No. 4:24-cv-00953-P

**JOINT NOTICE REGARDING DRAFT PROTECTIVE ORDER**

The parties respectfully submit this joint notice in anticipation of the January 14, 2025 hearing in this matter. The Court set the hearing in part because the Court anticipated that the parties may dispute the production of confidential information. ECF No. 51 at 1. The parties have conferred regarding a proposed protective order that would allow confidential information to be produced to both Plaintiffs and Intervenor-Defendant and, with one exception, have agreed on its terms.

Attached as Exhibit A is a draft protective order. The parties agree on every term except for one clause in Paragraph 4(d), which appears in redline. The parties' positions on the protective order are described below.

Federal Defendants' Position

Federal Defendants take no position on Paragraph 4(d) of the protective order, given Intervenor-Defendant's participation in this case.

Plaintiffs' Position

Marc Wagner is a member of Plaintiffs' litigation team and was admitted *pro hac vice* to this case two days after it was filed. ECF No. 18. Plaintiffs contend that he should be within the scope of persons who receive confidential information, along with the other litigators representing all parties to this case.

Intervenor Eli Lilly and Company (Lilly) proposes that a special disability applicable only to Plaintiffs be applied to exclude Mr. Wagner from the scope of persons who may receive confidential information, based solely on Mr. Wagner's title as general counsel of Plaintiff Outsourcing Facilities Association (OFA). That position is immaterial to any confidentiality concern. Mr. Wagner is not an employee of OFA and receives no compensation from OFA. He provides legal services to OFA as part of his work at Baker & Hostetler, which bills his time to OFA, as would be the case with outside counsel. His position with OFA consists of things like coordinating its lobbying and legal strategy efforts, taking minutes at board meetings, representing OFA at regulatory and industry meetings, and determining member eligibility. Mr. Wagner is not an employee of any competitor to Lilly. Lilly has not explained why the Protective Order's blanket ban on the use or dissemination of confidential information by any

attorney for any purpose outside this case (§5) provides insufficient protection for its interest in protecting confidential information.

Excluding Mr. Wagner from receiving confidential information will prejudice Plaintiffs. Mr. Wagner has a pharmacy degree and is a subject-matter expert who assists the generalist litigators in understanding information, including that to be disclosed under seal. This role is especially crucial for processing information on an expedited time-frame. FDA and Lilly certainly have subject matter experts involved in this case, and they are not proposed to be excluded from receiving confidential information – even if they advise Lilly as part of their legal work. Lilly’s proposed exclusion should be rejected.

Finally, if the Court is concerned about Mr. Wagner’s position as OFA’s general counsel, he is willing to resign from that position effective immediately to continue assistance in this case.

#### Intervenor-Defendant’s Position

Intervenor-Defendant Eli Lilly and Company (“Lilly”) objects to Plaintiffs’ proposed language to Section 4(d) of the Protective Order, which would allow confidential information to be viewed by the general counsel of Plaintiff Outsourcing Facilities Association (“OFA”) – Marc Wagner. Allowing Mr. Wagner to see Lilly’s internal, confidential information creates a serious risk of undue prejudice to Lilly and ethical dilemmas for Mr. Wagner, whereas precluding him from receiving Lilly’s confidential information will not prejudice Plaintiffs.

First, OFA is an organization that filed this suit to allow compounders to continue to make copies of Lilly's FDA-approved medicine. If Plaintiffs' language is accepted, OFA's general counsel will likely see detail on Lilly's production capabilities, distribution network, current and future plans to increase manufacturing capacity, and projections, among other competitively sensitive topics. Thus, highly sensitive information would be disclosed to an officer of an organization that represents Lilly's self-described competitors. See *United States v. Dentsply Int'l, Inc.*, 187 F.R.D. 152, 161-62 (D. Del. 1999) (precluding general counsel from receiving access to confidential information because, *inter alia*, the officer "could base future business decisions on information learned during discovery"); *Blanchard & Co. v. Barrick Gold Corp.*, 2004 WL 737485, at \*10 (E.D. La. Apr. 5, 2004) (imposing additional limitations in a protective order for commercially sensitive documents, because "[a]mple precedent exists for limiting disclosure of highly sensitive, confidential or proprietary information to outside attorneys and experts" and "the defendants' interest in . . . confidentiality . . . outweigh[ed] any interest . . . plaintiff ha[d] in securing [their] employees' ability to review this highly sensitive information"). Moreover, that access would be asymmetric: none of Lilly's corporate officers, its general counsel, or its other in-house counsel will receive access to any confidential data Plaintiffs submitted to FDA as part of the administrative record. OFA does not receive greater access to confidential commercial information simply by making one of its outside counsel a corporate officer as well (which is not isolated for OFA: another partner at outside counsel's firm, Lee Rosebush, serves as OFA's Executive Director).

*Second*, attorneys like Mr. Wagner, who wear two hats – one as OFA’s in-house counsel and as its outside counsel – will face an ongoing ethical conflict if they see Lilly’s internal information. “[I]t is very difficult for the human minds to compartmentalize and selectively suppress information once learned, no matter how well-intentioned the effort may be to do so.” *Gen. Elec. Co. v. Mitsubishi Heavy Indus., Ltd.*, 2011 WL 13202057, at \*4 (N.D. Tex. Feb. 10, 2011) (precluding in-house counsel from receiving confidential information). Acting as general counsel, Mr. Wagner will undoubtedly advise OFA on business and legal strategies and liaison with OFA’s members, including regarding their manufacture of unapproved copies of Lilly’s FDA-approved medicines. For this reason, courts often limit access to in-house lawyers acting as outside counsel in litigation because of the risk that counsel inadvertently use the information they learns for their client’s benefit. *See ST Sales Tech. Hldg., LLC v. Daimler Chrysler Co.*, 2008 WL 5634214, at \*3 (E.D. Tex. Mar. 14, 2008).

*Third*, Plaintiffs would not be materially prejudiced. This objection impacts one of five lawyers representing Plaintiffs. All Plaintiffs’ counsel have been involved in this case since the beginning, and are doubtlessly able to adequately represent OFA’s interests even if Mr. Wagner is unable to see confidential documents. Lastly, the conflict arising from Mr. Wagner’s two hats is of OFA’s own creation by positioning one of its outside counsel as an in-house corporate officer as well. OFA cannot claim prejudice resulting from the consequences of its own choice.

Accordingly, Lilly respectfully asks the Court to prohibit the parties' in-house counsel from receiving confidential documents or summaries of confidential documents.

DATED: JAN. 13, 2025

/s/ Andrew M. Grossman

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**CERTIFICATE OF SERVICE**

I hereby certify that this document, filed through the CM/ECF system, will be sent via electronic mail to the registered participants as identified on the Notice of Electronic Filing.

January 13, 2025

/s/ David H. Hixson  
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